

FORM PTO-1449 JUN 8 9 2004

INFORMATION DISCLOSURE STATEMENT

U.S. TRADEMARK OFFICE

ATTY. DOCKET NO.  
0942.375002/RWE/FRC  
FIRST NAMED INVENTOR  
Daley et al.  
FILING DATE  
November 20, 2003

APPLICATION NO.  
10/716,619

ART UNIT  
1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
TK	AA1	4,673,649	06/16/1987	Boyce et al.			07/15/1983
	AB1	4,767,704	08/30/1988	Cleveland et al.			10/07/1983
	AC1	4,927,762	05/22/1990	Darfler et al.			11/30/1988
	AD1	5,024,947	06/18/1991	Inlow et al.			07/24/1987
	AE1	5,045,454	09/03/1991	Bertheussen			02/23/1990
	AF1	5,061,620	10/29/1991	Tsukamoto et al.			03/30/1990
	AG1	5,063,157	11/05/1991	Stockinger			01/11/1989
	AH1	5,122,469	06/16/1992	Mather et al.			10/03/1990
	AI1	5,128,259	07/07/1992	Morgan et al.			10/27/1989
	AJ1	5,316,938	05/31/1994	Keen et al.			12/18/1992
▼	AK1	5,336,614	08/09/1994	Brown et al.			08/14/1991

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
TK	AL1	WO 92/05246	04/02/1992	WIPO			Yes
	AM1	WO 92/18615	10/29/1992	WIPO			No
	AN1	WO 95/02685	01/26/1995	WIPO			Yes
	AO1	WO 96/39487	12/12/1996	WIPO			No
▼	AP1	WO 97/34999	09/25/1997	WIPO			Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

TK	AR	1	Biddle, W., et al., "Cultivation and Ex Vivo Expansion of Human CD34+ Progenitor Cells Under Serum-Free Culture Conditions," in <i>Advances in Bone Marrow Purging and Processing: Fourth International Symposium</i> , Gee, A.P., et al., eds., Wiley-Liss, Inc., New York, pp. 351-361 (1994)
TK	AS	1	Biddle, W.C., et al., "Ex Vivo Expansion of Human Hematopoietic Progenitor Cells Under Serum-Free Conditions," in <i>Animal Cell Technology: Basic &amp; Applied Aspects</i> , Vol. 8, Funatsu, K., et al., eds., Kluwer Academic Publishers, Netherlands, pp. 25-40 (May 1997)
TK	AT	1	Bradley, T.R. and Metcalf, D., "The Growth of Mouse Bone Marrow Cells <i>In Vitro</i> ," <i>Aust. J. Exp. Biol. Med. Sci.</i> 44:287-300, University of Adelaide (1966)

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		FIRST NAMED INVENTOR <i>Daley et al.</i>			
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
TK	AA2	5,371,010	12/06/1994	Brown <i>et al.</i>			02/08/1994
	AB2	5,342,777	08/30/1994	Cole <i>et al.</i>			03/03/1992
	AC2	5,359,046	10/25/1994	Capon <i>et al.</i>			12/09/1992
	AD2	5,397,706	03/14/1995	Correa <i>et al.</i>			08/06/1993
	AE2	5,405,772	04/11/1995	Ponting			06/18/1993
	AF2	5,472,867	12/05/1995	Kanz <i>et al.</i>			09/29/1993
	AG2	5,474,931	12/12/1995	DiSorbo <i>et al.</i>			09/21/1993
	AH2	5,556,954	09/17/1995	Burn <i>et al.</i>			12/15/1992
	AI2	5,573,937	11/12/1996	Shinmoto <i>et al.</i>			01/09/1995
↓	AJ2	5,599,705	02/04/1997	Cameron, R.B.			11/16/1993
	AK2	5,766,951	06/16/1998	Brown <i>et al.</i>			11/12/1992

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
TK	AL2	WO 97/33978	09/18/1997	WIPO			Yes
	AM						No
	AN						Yes
	AO						No
	AP						Yes
							No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	2	Casadevall, N., <i>et al.</i> , "Erythroid Progenitors in Polycythemia Vera: Demonstration of Their Hypersensitivity to Erythropoietin Using Serum Free Cultures," <i>Blood</i> 59:447-451, American Society for Hematology (1982)
TK	AS	2	Civin, C.I., "Human Monomyeloid Cell Membrane Antigens," <i>Exp. Hematol.</i> 18:461-467, Elsevier Science Inc. (1990)
TK	AT	2	Collins, P.C., <i>et al.</i> , "Ex vivo culture systems for hematopoietic cells," <i>Curr. Opin. Biotech.</i> 7:223-230, Current Biology (April 1996)

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TK	AA3	5,817,773	10/06/1998	Wilson <i>et al.</i>			02/23/1996
	AB3	5,879,940	03/09/1999	Torok-Storb <i>et al.</i>			05/23/1997
	AC3	5,945,337	08/31/1999	Brown <i>et al.</i>			10/17/1997
↓	AD3	6,103,529	08/15/2000	Price <i>et al.</i>			10/10/1997
	AE3	6,383,810	05/07/2002	Fike <i>et al.</i>			02/13/1998
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TK	AR	3	Daley, J.P., <i>et al.</i> , "Ex Vivo Expansion of Human Hematopoietic Progenitor Cells in Serum-Free StemPro™-34 Medium," <i>Focus</i> 18:62-67, Life Technologies Inc (October 1996)
TK	AS	3	Daniel, C.P. and Dexter, T.M., "The role of growth factors in haemopoietic development: Clinical and biological implications," <i>Cancer &amp; Metastasis Rev.</i> 8:253-262, Kluwer Academic (1989)
TK	AT	3	de Wynter, E.A., <i>et al.</i> , "Comparison of Purity and Enrichment of CD34+ Cells from Bone Marrow, Umbilical Cord and Peripheral Blood (Primed for Apheresis) Using Five Separation Systems," <i>Stern Cells</i> 13:524-532, Karger (September 1995)

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TK	AR	4	Dexter, T.M., <i>et al.</i> , "Conditions Controlling the Proliferation of Haemopoietic Stem Cells <i>In Vitro</i> ," <i>J. Cell. Physiol.</i> 91:335-344, Wiley-Liss (1977)
TK	AS	4	Drouet, X., <i>et al.</i> , "Human liquid bone marrow culture in serum-free medium," <i>Brit. J. Haematol.</i> 73:143-147, Blackwell Scientific Publications (1989)
TK	AT	4	Eaves, C.J., <i>et al.</i> , "Methodology of Long-Term Culture of Human Hemopoietic Cells," <i>J. Tissue Cult. Meth.</i> 13:55-62, Tissue Culture Association (1991)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	5	Eliason, J.F. and Odartchenko, N., "Colony formation of primitive hemopoietic progenitor cells in serum-free medium," <i>Proc. Natl. Acad. Sci. USA</i> 82:775-779, National Academy of Sciences (1985)
TK	AS	5	Freshney, R.I., ed., in: <i>Culture of Animal Cells: A Manual of Basic Technique</i> , 2 <sup>nd</sup> Ed., Alan R. Liss, Inc., New York, NY, pp. 80-81 (1987)
TK	AT	5	GIBCO BRL, Life Technologies™, 1993-1994 Catalogue and Reference Guide, Life Technologies™, Inc., Gaithersburg, MD, pp. 1-2, 1-34, 1-38, 1-54, 1-70, 1-82, 1-99, 1-116, 4-43, 4-44, 4-45, 4-46, 4-59, 4-63, 5-3, and 5-4 (1993)
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	AP						Yes
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

TK	AR	6	Greenberg, H.M., <i>et al.</i> , "Human Granulocytes Generated in Continuous Bone Marrow Culture are Physiologically Normal," <i>Blood</i> 58:724-732, American Society of Hematology (1981)
TK	AS	6	Ham, R.G., "Clonal Growth of Mammalian Cells in a Chemically Defined, Synthetic Medium," <i>Proc. Natl. Acad. Sci. USA</i> 53:288-293, National Academy of Sciences (1965)
TK	AT	6	Ham, R.G., "Formulation of Basal Nutrient Media," in: <i>Methods for Preparation of Media, Supplements and Substrata for Serum-Free Animal Cell Culture</i> , Barnes, D.W., <i>et al.</i> , eds., Alan R. Liss, Inc., New York, NY, pp. 3-21 (1984)
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TK	AR	7	Haylock, D.N., et al., "Ex Vivo Expansion and Maturation of Peripheral Blood CD34 <sup>+</sup> Cells Into the Myeloid Lineage," <i>Blood</i> 80:1405-1412, American Society for Hematology (1992)
TK	AS	7	Iscove, N.N., "Culture of Lymphocytes and Hematopoietic Cells in Serum-Free Medium," in: <i>Methods for Serum-Free Culture of Neuronal and Lymphoid Cells</i> , Barnes, D.W., et al., eds., Alan R. Liss, Inc., New York, NY, pp. 169-185 (1984)
TK	AT	7	Koller, M.R. and Palsson, B.O., "Tissue Engineering: Reconstitution of Human Hematopoiesis Ex Vivo," <i>Biotechnol. &amp; Bioeng.</i> 42:909-930, Wiley Interscience (1993)

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TK	AR	<u>8</u>	Lambert, K.J. and Birch, J.R., "Cell Growth Media," in: <i>Animal Cell Biotechnology</i> , Vol. 1, Spier, R.E. and Griffiths, J.B., eds., Academic Press, London, UK, pp. 85-123 (1985)
TK	AS	<u>8</u>	Lebkowski, J.S., et al., "Serum-Free Culture of Hematopoietic Stem Cells: A Review," <i>Stem Cells</i> 13:607-612, AlphaMed Press (November 1995)
TK	AT	<u>8</u>	Maurer, H.R., "Towards Chemically-defined, Serum-free Media for Mammalian Cell Culture," in: <i>Animal cell culture: a practical approach</i> , Freshney, R.I., ed., IRL Press, Oxford, UK, pp. 13-31 (1986)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	9	McAdams, T.A., et al., "Hematopoietic cell culture therapies (Part I): cell culture considerations," <i>Trends Biotech.</i> 14:341-349, Elsevier Science Publishers (September 1996)
TK	AS	9	Migliaccio, G., et al., "The Biology of Hematopoietic Growth Factors: Studies in vitro under Serum-deprived Conditions," <i>Exp. Hematol.</i> 18:1049-1055, Elsevier Science Inc. (1990)
TK	AT	9	Migliaccio, G. and Migliaccio, A.R., "Serum-Deprived Cultures of Primary Hematopoietic Cells," in: <i>Culture of Specialized Cells: Culture of Hematopoietic Cells</i> , Freshney, R.I., et al., eds., Wiley-Liss, Inc., Somerset, NJ, pp. 81-98 (1994)

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	AN						Yes
	AO						No
	AP						Yes
							No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	<u>10</u>	PCT Gazette, WO 98/00521, International Bureau of the World Intellectual Property Organization Under the Patent Cooperation Treaty, p. 275 (January 1998)
TK	AS	<u>10</u>	Sandstrom, C.E., et al., "Review: Serum-Free Media for Cultures of Primitive and Mature Hematopoietic Cells," <i>Biotechnol. &amp; Bioeng.</i> 43:706-733, Wiley Interscience (1994)
TK	AT	<u>10</u>	Schain, L.R., et al., "Animal Serum-Free Culture of Purified Human CD34+ Cells: Amplification of Progenitors from G-CSF and GM-CSF-Mobilized Peripheral Blood," <i>J. Hematother.</i> 6:335-349, Mary Ann Liebert, Inc. (August 1997)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	11	Sigma® Chemical Co., "Tissue Culture Media and Reagents," in: <i>Sigma® Chemical Company Catalog</i> , Sigma® Chemical Co., St. Louis, MO, pp. 1142, 1470, and 1475 (1989)
TK	AS	11	Sigma® Chemical Co., "Tissue Culture Media and Reagents," <i>Sigma® Chemical Company Catalog</i> , Sigma® Chemical Co., St. Louis, MO, pp. 1495, 1512, 1514, and 1516 (1994)
TK	AT	11	Sonoda, Y., et al., "Analysis in serum-free culture of the targets of recombinant human hemopoietic growth factors: Interleukin 3 and granulocyte/macrophage-colony-stimulating factor are specific for early development stages," <i>Proc. Natl. Acad. Sci. USA</i> 85:4360-4364, National Academy of Sciences (1988)

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TK	AR	<u>12</u>	Steen, R., et al., "c-kit Ligand Combined with GM-CSF and/or IL-3 Can Expand CD34 <sup>+</sup> Hematopoietic Progenitor Subsets for Several Weeks In Vitro," <i>Stem Cells</i> 12:214-224, Karger (1994)
TK	AS	<u>12</u>	"StemPro™-34 SFM," <i>Spectrum</i> , Life Technologies, Inc., p. 12 (May 1996)
TK	AT	<u>12</u>	Traycoff, C.M., et al., "Rapid exit from G <sub>0</sub> /G <sub>1</sub> phases of cell cycle in response to stem cell factor confers on umbilical cord blood CD34 <sup>+</sup> cells an enhanced ex vivo expansion potential," <i>Exp. Hematol.</i> 22:1264-1272, Elsevier Science Inc. (1994)

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	AL						Yes
	AM						No
	AN						Yes
	AO						No
	AP						Yes
							No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	13	Zang, M., et al., "Production of Recombinant Proteins in Chinese Hamster Ovary Cells Using a Protein-Free Cell Culture Medium," <i>Bio/Tech.</i> 13:389-392, Nature Publishing Company (April 1995)
TK	AS	13	Copy of Co-Pending United States Patent Application No. 09/028,514, Gorfien et al., filed February 23, 1998
TK	AT	13	International Search Report for International Patent Appl. No. PCT/US97/01867, mailed June 5, 1997, European Patent Office, Netherlands

EXAMINER	/Taeyoon Kim/	DATE CONSIDERED 10/30/2006
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 0942.3750002/RWE/FRC	APPLICATION NO. 10/716,619
		FIRST NAMED INVENTOR Daley et al.	
		FILING DATE November 20, 2003	ART UNIT 1632

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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	AM						No
	AN						Yes
	AO						No
	AP						Yes
							No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	14	Gruber D.F. and Jayme, D.W., "Cell and Tissue Culture Media: History and Terminology," in: <i>Cell Biology: A Laboratory Handbook</i> , Celis, J.E., ed., Academic Press, Inc., San Diego, CA, pp. 451-458 (1994)
TK	AS	14	Ham, R.G. and McKeehan, W.L., "Media and Growth Requirements," <i>Meth. Enzymol.</i> 58:44-93, Academic Press (1979)
TK	AT	14	Jayne, D.W. and Gruber, D.F., "Development of Serum-Free Media and Methods for Optimization of Nutrient Composition," in: <i>Cell Biology: A Laboratory Handbook</i> , Celis, J.E., ed., Academic Press, Inc., San Diego, CA, pp. 18-24 (1994)

EXAMINER	/Taeyoon Kim/	DATE CONSIDERED
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FORM PTO-1449 <b>INFORMATION DISCLOSURE STATEMENT</b>		ATTY. DOCKET NO. 0942.3750002/RWE/FRC	APPLICATION NO. 10/716,619
		FIRST NAMED INVENTOR <i>Daley et al.</i>	
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**FOREIGN PATENT DOCUMENTS**

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

TK	AR	15	Kohn, D.B., et al., "Engraftment of gene-modified umbilical cord blood cells in neonates with adenosine deaminase deficiency," <i>Nat. Med.</i> 1:1017-1023, Nature Publishing Company (October 1995)
	AS		
	AT		

EXAMINER	/Taeyoon Kim/	DATE CONSIDERED 10/30/2006
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FORM PTO-1449

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENTATTY. DOCKET NO.  
0942.3750002/RWE/FRCAPPLICATION NO.  
10/716,619FIRST NAMED INVENTOR  
Daley et al.FILING DATE  
November 20, 2003ART UNIT  
1632**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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PATENT & TRADEMARK OFFICE	AC					
	AD					
	AE					
	AF					
	AG					
	AH					
	AI					
	AJ					
	AK					

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL					Yes No
TK	AM2	WO 95/06112	03/02/1995	WIPO		Yes No
	AN					Yes No
	AO					Yes No
	AP					Yes No

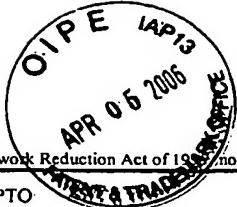
**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

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EXAMINER	/Taeyoon Kim/	DATE CONSIDERED
		10/27/2006

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**SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
*(Use as many sheets as necessary)*

Sheet

1 of 1

**Complete if Known**

Application Number	10/716,619
Filing Date	November 20, 2003
First Named Inventor	John P. Daley
Art Unit	1632
Examiner Name	Falk, A.M.

Attorney Docket Number

0942.3750002/SRL/FRC

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
TK	AS15	Iscove, N.N. and Melchers, F., "Complete Replacement of Serum by Albumin, Transferrin, and Soybean Lipid in Cultures of Lipopolysaccharide-Reactive B Lymphocytes," <i>J. Exp. Med.</i> 147:923-933, The Rockefeller University Press (1978)	
TK	AT15	Iscove, N.N., <i>et al.</i> , "Complete Replacement of Serum in Primary Cultures of Erythropoietin-Dependent Red Cell Precursors (CFU-E) by Albumin, Transferrin, Iron, Unsaturated Fatty Acid, Lecithin and Cholesterol," <i>Exp. Cell Res.</i> 126:121-126, Academic Press, Inc. (1980)	
TK	AR16	Lansdorp, P.M., <i>et al.</i> , "Ontogeny-related Changes in Proliferative Potential of Human Hematopoietic Cells," <i>J. Exp. Med.</i> 178:787-791, The Rockefeller University Press (1993)	
TK	AS16	Lansdorp, P.M. and Dragowska, W., "Long-Term Erythropoiesis from Constant Numbers of CD34 <sup>+</sup> Cells in Serum-free Cultures Initiated with Highly Purified Progenitor Cells from Human Bone Marrow," <i>J. Exp. Med.</i> 175:1501-1509, The Rockefeller University Press (1992)	
TK	AT16	Mayani, H., <i>et al.</i> , "Cytokine-Induced Selective Expansion and Maturation of Erythroid Versus Myeloid Progenitors from Purified Cord Blood Precursor Cells," <i>Blood</i> 81:3252-3258, American Society of Hematology (1993)	

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Examiner Signature	/Taeyoon Kim/	Date Considered	10/27/2006
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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.